APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/613,591	07/10/00	BOYLE	W A-378CIP5

021069 HM12/0928	**EXAMINER**
AMGEN INCORPORATED	DEBERRY, R

ART UNIT	PAPER NUMBER
1647	16

AMGEN INCORPORATED
MAIL STOP 27-4-A
ONE AMGEN CENTER DRIVE
THOUSAND OAKS CA 91320-1799

DATE MAILED:
09/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trade marks

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.

EXAMINER

ART UNIT	PAPER
	15

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents

The communication filed 08 August 2001 is not fully responsive to the Office communication mailed 24 July 2001 for the reason(s) set forth on the attached Notice To Comply With The Sequence Rules or CRF Diskette Problem Report. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Since the reply appears to be <u>bona fide</u> attempt to comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825), applicant is given a TIME PERIOD of **ONE (1) MONTH** from the mailing date of this communication within which to correct the deficiency so as to comply with the sequence rules (37 CFR 1.821 - 1.825) in order to avoid abandonment of the application under 37 CFR 1.821(g). EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

Any inquiry concerning this communication should be directed to Examiner **Regina M. DeBerry**, Art Unit 1647, whose telephone number is (703) 305-6915.
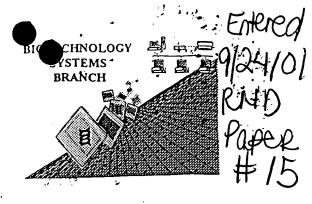
Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.

ELIZABETH KEMMERER
PRIMARY EXAMINER

TO-90C (Rev.3-98)

Notice to Comply	Application No.		Applicant(s)	
	09/613,591		BOYLE ET AL.	
	Examiner		Art Unit	
	Regina M. DeBerry		1647	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☒ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other:

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
PatentIn Software Program Support
    Technical Assistance......................................703-287-0200
    To Purchase PatentIn Software.......................703-306-2600

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY

RAW SEQUENCE LISTING
ERROR REPORT

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number: _09/613,591 C_

Source: _OIPE_

Date Processed by STIC: _08/15/2001_

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.
PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:
1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,
2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY
FOR CRF SUBMISSION QUESTIONS, PLEASE CONTACT MARK SPENCER, 703-308-4212.

FOR SEQUENCE RULES INTERPRETATION, PLEASE CONTACT ROBERT WAX, 703-308-4216.
PATENTIN 2.1 e-mail help: patin21help@uspto.gov or phone 703-306-4119 (R. Wax)
PATENTIN 3.0 e-mail help: patin3help@uspto.gov or phone 703-306-4119 (R. Wax)

TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE <u>CHECKER VERSION 3.0 PROGRAM</u>, ACCESSIBLE THROUGH THE U.S. PATENT AND TRADEMARK OFFICE WEBSITE. SEE BELOW:

Checker Version 3.0

The Checker Version 3.0 application is a state-of-the-art Windows based software program employing a logical and intuitive user-interface to check whether a sequence listing is in compliance with format and content rules. Checker Version 3.0 works for sequence listings generated for the original version of 37 CFR §§1.821 – 1.825 effective October 1, 1990 (old rules) and the revised version (new rules) effective July 1, 1998 as well as World Intellectual Property Organization (WIPO) Standard ST.25.
Checker Version 3.0 replaces the previous DOS-based version of Checker, and is Y2K-compliant. Checker allows public users to check sequence listings in Computer Readable form (CRF) before submitting them to the United States Patent and Trademark Office (USPTO).
Use of Checker prior to filing the sequence listing is expected to result in fewer errored sequence listings, thus saving time and money.

<u>Checker Version 3.0 can be down loaded from the USPTO website at the following address:</u>
http://www.uspto.gov/web/offices/pac/checker

Raw Sequence Listing Error Summary

ATTN: NEW RULES CASES: PLEASE DISREGARD ENGLISH "ALPHA" HEADERS, WHICH WERE INSERTED BY PTO SOFTWARE

1 ____ Wrapped Nucleics   The number/text at the end of each line "wrapped" down to the next line. This may occur if your file
   Wrapped Aminos ·   was retrieved in a word processor after creating it. Please adjust your right margin to .3; this will
   prevent "wrapping."

2 ____ Invalid Line Length   The rules require that a line not exceed 72 characters in length. This includes white spaces.

3 ____ Misaligned Amino   The numbering under each 5th amino acid is misaligned. Do not use tab codes between numbers;
   Numbering   use space characters, instead.

4 ____ Non-ASCII   The submitted file was not saved in ASCII(DOS) text, as required by the Sequence Rules. Please
   ensure your subsequent submission is saved in ASCII text.

5 ____ Variable Length   Sequence(s)____ contain n's or Xaa's representing more than one residue. Per Sequence Rules,
   each n or Xaa can only represent a single residue. Please present the maximum number of each
   residue having variable length and indicate in the <220>-<223> section that some may be missing.

6 ____ PatentIn 2.0   A "bug" in PatentIn version 2.0 has caused the <220>-<223> section to be missing from amino acid
   "bug"   sequences(s) _____. Normally, PatentIn would automatically generate this section from the
   previously coded nucleic acid sequence. Please manually copy the relevant <220>-<223> section to
   the subsequent amino acid sequence. This applies to the mandatory <220>-<223> sections for
   Artificial or Unknown sequences.

7 ____ Skipped Sequences   Sequence(s) ____ missing. If intentional, please insert the following lines for each skipped sequence:
   (OLD RULES)   (2) INFORMATION FOR SEQ ID NO:X: (insert SEQ ID NO where "X" is shown)
   (i)   SEQUENCE CHARACTERISTICS: (Do not insert any subheadings under this heading)
   (xi) SEQUENCE DESCRIPTION:SEQ ID NO:X: (insert SEQ ID NO where "X" is shown)
   This sequence is intentionally skipped

   Please also adjust the "(ii) NUMBER OF SEQUENCES:" response to include the skipped sequences.

8 ____ Skipped Sequences   Sequence(s) ____ missing. If intentional, please insert the following lines for each skipped sequence.
   (NEW RULES)   <210> sequence id number
   <400> sequence id number
   000

9 ____ Use of n's or Xaa's   Use of n's and/or Xaa's have been detected in the Sequence Listing.
   (NEW RULES)   Per 1.823 of Sequence Rules, use of <220>-<223> is MANDATORY if n's or Xaa's are present.
   In <220> to <223> section, please explain location of n or Xaa, and which residue n or Xaa represents.

10 ____ Invalid <213>   Per 1.823 of Sequence Rules, the only valid <213> responses are: Unknown, Artificial Sequence, or
   Response   scientific name (Genus/species). <220>-<223> section is required when <213> response is Unknown or
   is Artificial Sequence

11 _✓_ Use of <220>   Sequence(s) _____ missing the <220> "Feature" and associated numeric identifiers and responses.
   Use of <220> to <223> is MANDATORY if <213> "Organism" response is "Artificial Sequence" or
   "Unknown." Please explain source of genetic material in <220> to <223> section.
   (See "Federal Register," 06/01/1998, Vol. 63, No. 104, pp. 29631-32)   (Sec. 1.823 of Sequence Rules)

12 ____ PatentIn 2.0   Please do not use "Copy to Disk" function of PatentIn version 2.0. This causes a corrupted file,
   "bug"   resulting in missing mandatory numeric identifiers and responses (as indicated on raw sequence
   listing). Instead, please use "File Manager" or any other manual means to copy file to floppy disk.

Re-run●

```
        RAW SEQUENCE LISTING              DATE: 08/15/2001
        PATENT APPLICATION:  US/09/613,591C    TIME: 14:46:44

        Input Set : A:\A-378CIP5.ST25.txt
        Output Set: N:\CRF3\08152001\I613591C.raw
```

Does Not Comply
Corrected Diskette Needed

See page 6 of 7A

```
 3 <110> APPLICANT: BOYLE, WILLIAM J. ,
 4        LACEY, DAVID LEE
 5        CALZONE, FRANK J.
 6        CHANG, MING-SHI
 7        SENALDI, GIORGIO
 9 <120> TITLE OF INVENTION: COMBINATION THERAPY FOR CONDITIONS LEADING TO BONE LOSS——
11 <130> FILE REFERENCE: A-378CIP5
13 <140> CURRENT APPLICATION NUMBER: US 09/613,591C
14 <141> CURRENT FILING DATE: 2000-07-10
16 <150> PRIOR APPLICATION NUMBER: US 09/457,647
17 <151> PRIOR FILING DATE: 1999-12-09
19 <150> PRIOR APPLICATION NUMBER: US 09/350,670
20 <151> PRIOR FILING DATE: 1999-07-09
22 <150> PRIOR APPLICATION NUMBER: US 08/706,945
23 <151> PRIOR FILING DATE: 1996-09-03
25 <150> PRIOR APPLICATION NUMBER: US 08/577,788
26 <151> PRIOR FILING DATE: 1995-12-22
28 <160> NUMBER OF SEQ ID NOS: 168
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32 <210> SEQ ID NO: 1
33 <211> LENGTH: 36
34 <212> TYPE: DNA
35 <213> ORGANISM: Artificial Sequence
37 <220> FEATURE:
38 <223> OTHER INFORMATION: Not I restriction site
40 <220> FEATURE:
41 <221> NAME/KEY: misc_feature
42 <222> LOCATION: (28)..(35)
43 <223> OTHER INFORMATION: N = any random nucleic acid
46 <400> SEQUENCE: 1
W--> 47 aaaggaagga aaaaagcggc cgctacannn nnnnnt                    36
50 <210> SEQ ID NO: 2
51 <211> LENGTH: 16
52 <212> TYPE: DNA
53 <213> ORGANISM: Artificial Sequence
55 <220> FEATURE:
56 <223> OTHER INFORMATION: Not I restriction site
58 <400> SEQUENCE: 2
59 tcgacccacg cgtccg                                            16
62 <210> SEQ ID NO: 3
63 <211> LENGTH: 12
64 <212> TYPE: DNA
65 <213> ORGANISM: Artificial Sequence
67 <220> FEATURE:
68 <223> OTHER INFORMATION: Not I restriction site
70 <400> SEQUENCE: 3
71 gggtgcgcag gc                                                12
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RAW SEQUENCE LISTING   DATE: 08/15/2001
PATENT APPLICATION: US/09/613,591C   TIME: 14:46:44

Input Set : A:\A-378CIP5.ST25.txt
Output Set: N:\CRF3\08152001\I613591C.raw

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 76 <212> TYPE: DNA
 77 <213> ORGANISM: Artificial Sequence
 79 <220> FEATURE:
 80 <223> OTHER INFORMATION: Not I restriction site
 82 <400> SEQUENCE: 4
 83 tgtaaaacga cggccagt                                    18
 86 <210> SEQ ID NO: 5
 87 <211> LENGTH: 18
 88 <212> TYPE: DNA
 89 <213> ORGANISM: Artificial Sequence
 91 <220> FEATURE:
 92 <223> OTHER INFORMATION: Not I restriction site
 94 <400> SEQUENCE: 5
 95 caggaaacag ctatgacc                                    18
 98 <210> SEQ ID NO: 6
 99 <211> LENGTH: 20
100 <212> TYPE: DNA
101 <213> ORGANISM: Artificial Sequence
103 <220> FEATURE:
104 <223> OTHER INFORMATION: Not I restriction site
106 <400> SEQUENCE: 6
107 caattaaccc tcactaaagg                                  20
110 <210> SEQ ID NO: 7
111 <211> LENGTH: 23
112 <212> TYPE: DNA
113 <213> ORGANISM: Rattus rattus
115 <400> SEQUENCE: 7
116 gcattatgac ccagaaaccg gac                              23
119 <210> SEQ ID NO: 8
120 <211> LENGTH: 23
121 <212> TYPE: DNA
122 <213> ORGANISM: Rattus rattus
124 <400> SEQUENCE: 8
125 aggtagcgcc cttcctcaca ttc                              23
128 <210> SEQ ID NO: 9
129 <211> LENGTH: 30
130 <212> TYPE: DNA
131 <213> ORGANISM: Artificial Sequence
133 <220> FEATURE:
134 <223> OTHER INFORMATION: Oligonucleotide primer
136 <400> SEQUENCE: 9
137 gactagtccc acaatgaaca agtggctgtg                       30
140 <210> SEQ ID NO: 10
141 <211> LENGTH: 45
142 <212> TYPE: DNA
143 <213> ORGANISM: Artificial Sequence
145 <220> FEATURE:
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RAW SEQUENCE LISTING   DATE: 08/15/2001
PATENT APPLICATION: US/09/613,591C   TIME: 14:46:44

Input Set : A:\A-378CIP5.ST25.txt
Output Set: N:\CRF3\08152001\I613591C.raw

146 <223> OTHER INFORMATION: Oligonucleotide primer
148 <400> SEQUENCE: 10
149 ataagaatgc ggccgctaaa ctatgaaaca gcccagtgac cattc   45
152 <210> SEQ ID NO: 11
153 <211> LENGTH: 21
154 <212> TYPE: DNA
155 <213> ORGANISM: Artificial Sequence
157 <220> FEATURE:
158 <223> OTHER INFORMATION: Oligonucleotide primer
160 <400> SEQUENCE: 11
161 gcctctagaa agagctggga c   21
164 <210> SEQ ID NO: 12
165 <211> LENGTH: 21
166 <212> TYPE: DNA
167 <213> ORGANISM: Artificial Sequence
169 <220> FEATURE:
170 <223> OTHER INFORMATION: Oligonucleotide primer
172 <400> SEQUENCE: 12
173 cgccgtgttc catttatgag c   21
176 <210> SEQ ID NO: 13
177 <211> LENGTH: 24
178 <212> TYPE: DNA
179 <213> ORGANISM: Rattus rattus
181 <400> SEQUENCE: 13
182 atcaaaggca gggcatactt cctg   24
185 <210> SEQ ID NO: 14
186 <211> LENGTH: 24
187 <212> TYPE: DNA
188 <213> ORGANISM: Rattus rattus
190 <400> SEQUENCE: 14
191 gttgcactcc tgtttcacgg tctg   24
194 <210> SEQ ID NO: 15
195 <211> LENGTH: 24
196 <212> TYPE: DNA
197 <213> ORGANISM: Rattus rattus
199 <400> SEQUENCE: 15
200 caagacacct tgaagggcct gatg   24
203 <210> SEQ ID NO: 16
204 <211> LENGTH: 24
205 <212> TYPE: DNA
206 <213> ORGANISM: Rattus rattus
208 <400> SEQUENCE: 16
209 taacttttac agaagagcat cagc   24
212 <210> SEQ ID NO: 17
213 <211> LENGTH: 33
214 <212> TYPE: DNA
215 <213> ORGANISM: Rattus rattus
217 <400> SEQUENCE: 17
218 agcgcggccg catgaacaag tggctgtgct gcg   33

RAW SEQUENCE LISTING
PATENT APPLICATION: US/09/613,591C

DATE: 08/15/2001
TIME: 14:46:44

Input Set : A:\A-378CIP5.ST25.txt
Output Set: N:\CRF3\08152001\I613591C.raw

```
221 <210> SEQ ID NO: 18
222 <211> LENGTH: 31
223 <212> TYPE: DNA
224 <213> ORGANISM: Rattus rattus
226 <400> SEQUENCE: 18
227 agctctagag aaacagccca gtgaccattc c                             31
230 <210> SEQ ID NO: 19
231 <211> LENGTH: 24
232 <212> TYPE: DNA
233 <213> ORGANISM: Rattus rattus
235 <400> SEQUENCE: 19
236 gtgaagctgt gcaagaacct gatg                                     24
239 <210> SEQ ID NO: 20
240 <211> LENGTH: 24
241 <212> TYPE: DNA
242 <213> ORGANISM: Rattus rattus
244 <400> SEQUENCE: 20
245 atcaaaggca gggcatactt cctg                                     24
248 <210> SEQ ID NO: 21
249 <211> LENGTH: 24
250 <212> TYPE: DNA
251 <213> ORGANISM: Homo sapiens
253 <400> SEQUENCE: 21
254 cagatcctga agctgctcag tttg                                     24
257 <210> SEQ ID NO: 22
258 <211> LENGTH: 33
259 <212> TYPE: DNA
260 <213> ORGANISM: Homo sapiens
262 <400> SEQUENCE: 22
263 agcgcggccg cggggaccac aatgaacaag ttg                           33
266 <210> SEQ ID NO: 23
267 <211> LENGTH: 33
268 <212> TYPE: DNA
269 <213> ORGANISM: Homo sapiens
271 <400> SEQUENCE: 23
272 agctctagaa ttgtgaggaa acagctcaat ggc                           33
275 <210> SEQ ID NO: 24
276 <211> LENGTH: 39
277 <212> TYPE: DNA
278 <213> ORGANISM: Artificial Sequence
280 <220> FEATURE:
281 <223> OTHER INFORMATION: Not I restriction site
283 <400> SEQUENCE: 24
284 atagcggccg ctgagcccaa atcttgtgac aaaactcac                     39
287 <210> SEQ ID NO: 25
288 <211> LENGTH: 45
289 <212> TYPE: DNA
290 <213> ORGANISM: Artificial Sequence
292 <220> FEATURE:
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RAW SEQUENCE LISTING
PATENT APPLICATION: US/09/613,591C

DATE: 08/15/2001
TIME: 14:46:44

Input Set : A:\A-378CIP5.ST25.txt
Output Set: N:\CRF3\08152001\I613591C.raw

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293 <223> OTHER INFORMATION: Not I restriction site
295 <400> SEQUENCE: 25
296 tctagagtcg acttatcatt tacccggaga cagggagagg ctctt                      45
299 <210> SEQ ID NO: 26
300 <211> LENGTH: 38
301 <212> TYPE: DNA
302 <213> ORGANISM: Mus musculus
304 <400> SEQUENCE: 26
305 cctctgagct caagcttccg aggaccacaa tgaacaag                              38
308 <210> SEQ ID NO: 27
309 <211> LENGTH: 43
310 <212> TYPE: DNA
311 <213> ORGANISM: Mus musculus
313 <400> SEQUENCE: 27
314 cctctgcggc cgctaagcag cttattttca cggattgaac ctg                       43
317 <210> SEQ ID NO: 28
318 <211> LENGTH: 38
319 <212> TYPE: DNA
320 <213> ORGANISM: Mus musculus
322 <400> SEQUENCE: 28
323 cctctgagct caagcttccg aggaccacaa tgaacaag                              38
326 <210> SEQ ID NO: 29
327 <211> LENGTH: 24
328 <212> TYPE: DNA
329 <213> ORGANISM: Homo sapiens
331 <400> SEQUENCE: 29
332 tccgtaagaa acagcccagt gacc                                            24
335 <210> SEQ ID NO: 30
336 <211> LENGTH: 31
337 <212> TYPE: DNA
338 <213> ORGANISM: Mus musculus
340 <400> SEQUENCE: 30
341 cctctgcggc cgctgttgca tttcctttct g                                    31
344 <210> SEQ ID NO: 31
345 <211> LENGTH: 19
346 <212> TYPE: PRT
347 <213> ORGANISM: Mus musculus
349 <400> SEQUENCE: 31
351 Glu Thr Leu Pro Pro Lys Tyr Leu His Tyr Asp Pro Glu Thr Gly His
352 1               5                   10                  15
355 Gln Leu Leu
359 <210> SEQ ID NO: 32
360 <211> LENGTH: 21
361 <212> TYPE: DNA
362 <213> ORGANISM: Mus musculus
364 <400> SEQUENCE: 32
365 tcccttgccc tgaccactct t                                              21
368 <210> SEQ ID NO: 33
369 <211> LENGTH: 34
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<210> SEQ ID NO 116
<211> LENGTH: 94
<212> TYPE: DNA
<213> ORGANISM: Artificial Sequence
<220> FEATURE:
<223> OTHER INFORMATION: :

Description of Artificial Sequence is required in field 223.

<400> SEQUENCE: 116

ccggcggaca tttatcacac agcagctgat gactagtttc ttcatcataa tgaagatatt
60

ttggagcaaa agtttccata tgttattcct cctt
94

VERIFICATION SUMMARY   DATE: 08/15/2001
PATENT APPLICATION: US/09/613,591C   TIME: 14:46:45

Input Set : A:\A-378CIP5.ST25.txt
Output Set: N:\CRF3\08152001\I613591C.raw

L:47 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:1
L:1461 M:220 C: Keyword misspelled or invalid format, <213> ORGANISM for SEQ ID#:116
L:1463 M:258 W: Mandatory Feature missing, <220> FEATURE:
L:1463 M:258 W: Mandatory Feature missing, <223> OTHER INFORMATION: *Errored*